DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 23, 2015

SterilMed
% Dr. Sew-Wah Tay
Libra Medical
8401 73rd Avenue North, Suite 63
Brooklyn Park, Minnesota 55428

Re: K143260
Trade/Device Name: Reprocessed Vessel Sealers
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: January 23, 2015
Received: January 26, 2015

Dear Dr. Tay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Models Subject to Clearance:

Model Number	Device Description	Shaft Diameter	Shaft Length	Shaft Rotation
LF1637	Reprocessed Covidien Ligasure 5 mm, Blunt Tip, Laparoscopic Sealer/Divider	5 mm	37 cm	180°

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143260

Device Name

Reprocessed Vessel Sealers

Indications for Use *(Describe)*

The reprocessed vessel sealer/dividers are intended for use in general and gynecological laparoscopic surgical procedures where ligation and division of vessels and lymph is desired.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of the vessels is performed. These procedures include laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The reprocessed vessel sealer/dividers can be used to on vessels and lymphatics up to and including 7 mm, and tissue bundles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter and Manufacturer:	Nicole Boser Sterilmed, Inc. 5010 Cheshire Parkway N, Suite 2 Plymouth, MN 55446
Manufacturing Facility Address:	11400 73rd Avenue North Maple Grove, MN 55369
Primary Contact:	Sew-Wah Tay PhD Libra Medical, Inc. Tel: 612-801-6782 Fax: 763-477-6357 Email: swtay@libramed.com
Secondary Contacts:	Nicole Boser Tel: (763) 488-2050 Fax: (763) 488-3441 Email: nboser@sterilmed.com
Date of Submission:	12 November 2014
Trade Name:	Reprocessed Vessel Sealer
Regulation Name:	Electrosurgical, cutting & coagulation accessories, laparoscopic & endoscopic, reprocessed
Regulation Number	21 CFR 878.4400
Device Classification:	Class II
Product Code:	NUJ

Predicate Devices:	Covidien LigaSure™ 5 mm, Blunt Tip Laparoscopic Sealer/Divider (K130744). Sterilmed Reprocessed Vessel Sealer (K123096)
Device Description:	The reprocessed vessel sealer is a sterile, hand-held bipolar RF electrosurgical instrument designed exclusively for use with the ForceTriad™ energy platform (generator) to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics clamped between the jaws, grasping tissue, and blunt dissection during laparoscopic general surgical procedures (as indicated) using radio frequency (RF) energy. A hand actuated lever allows the user to open and close the instrument jaws, and includes a latching mechanism that holds the jaws in the closed position during vessel sealing and cutting.

Intended Use:	The reprocessed vessel sealer/dividers are intended for use in general and gynecological laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of the vessels is performed. These procedures include laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures. The reprocessed vessel sealer/dividers can be used to on vessels and lymphatics up to and including 7 mm, and tissue bundles.
Technological Characteristics:	The reprocessed vessel sealer has the same technological and performance characteristics as the predicate, K130744. Similar to the predicate, this reprocessed device seals vessels and lymphatics using radio frequency (RF) energy to achieve its intended use and can mechanically divide the sealed areas or tissue with a mechanical cutting device. The manner of reprocessing and testing is identical to predicate K123096, Sterilmed reprocessed vessel sealer.
Functional and Safety Testing:	Representative samples of reprocessed devices were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F2096), and shelf-life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, and fatigue testing. Testing performed: • Electrical Safety (IEC 60601-2-2) • Device Functionality • Vessel Seal Burst (Static and Burst Pressure) • Vessel Seal Thermal Spread • Mold Stress • Drop • Spillage • Push Performance testing shows the reprocessed vessel sealers to perform as originally intended.
Conclusion:	Sterilmed concludes that the reprocessed vessel sealer is safe, effective, and substantially equivalent to the predicate device, Covidien LigaSure™ 5 mm, Blunt Tip, Laparoscopic Sealer/Divider (K130744), as described in this premarket notification submission. The reprocessing and validation methods used are similar to the Sterilmed reprocessed vessel sealer predicate device (K123096).